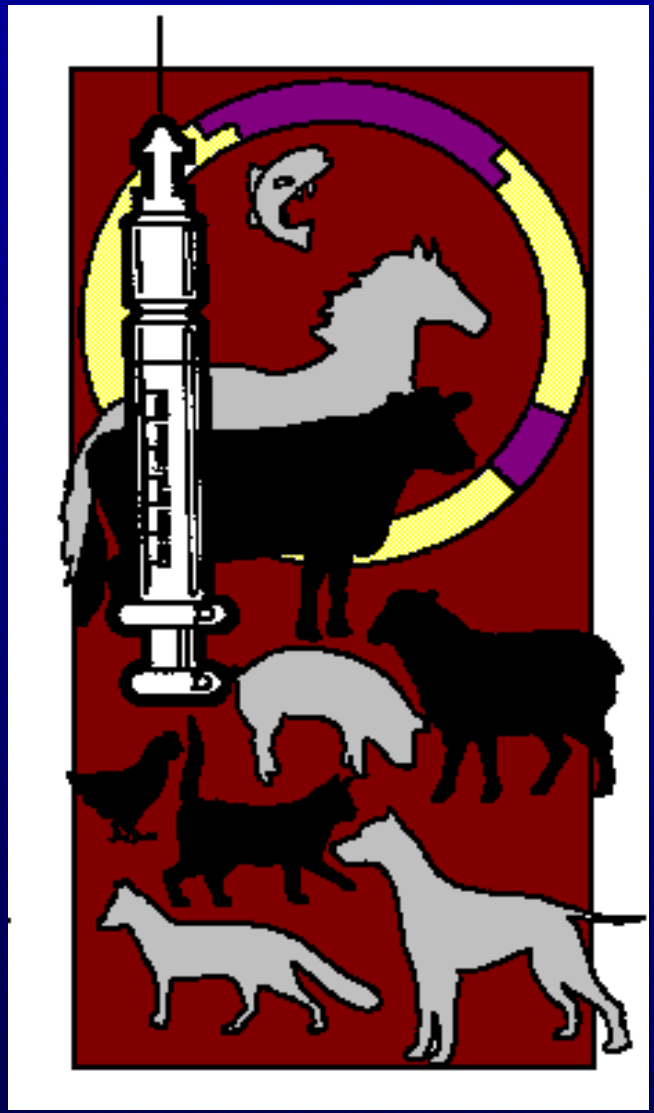
VICH - International Harmonization of Standards for Veterinary Biologics



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United States Department of Agriculture
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VICH

- International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
- Est. 1996 following discussions at ITCVDR and OIE
- Trilateral (EU-Japan-USA) program

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VICH
Harmonization Activity

- Licensing/registration
  - procedures & requirements
- Production facilities
  - standards & inspection
- Products
  - production, testing, references & reagents, records, release, nomenclature, labeling, monitoring
- Compliance

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VICH - Objectives

- To provide a forum for a constructive dialogue between regulatory authorities and the veterinary medicinal products industry on the real and perceived differences in the technical requirements for product registration in the EU, Japan, and the USA, with the expectation that such a process may serve as catalyst for a wider international harmonization;

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VICH - Objectives

- To identify areas where modifications in technical requirements or greater mutual acceptance of research and developmental procedures could lead to a more economical use of human, animal, and material resources, without compromising safety;

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VICH - Objectives

- To make recommendations on practical ways to achieve harmonization in technical requirements affecting registration of veterinary products and to implement these recommendations in the three regions. Once adopted the VICH recommendations should replace corresponding regional requirements. These recommendations should focus on the essential scientific requirements needed to address a topic and should eliminate unnecessary or redundant requirements;

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VICH - Objectives

- The VICH should be conducted in a transparent and cost effective manner and should provide the opportunity for public comment on recommendations at the draft stage.

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VICH - Membership

	Government	Industry
Members	EU Japan USA	FEDESA JVPA AHI
Observers	Aust./NZ	Avcare/Agcarm
Associate	OIE	
Chair	Rotates	
Secretariat		COMISA

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VICH - 9th Steering Committee Meeting

- London UK, June 2001
- Results
  - Working group reports
  - Review of guideline implementation and consultation procedures in the regions
  - Debate over application to "new" or "existing" products.
  - Guidelines released for consultation (Step 4) and implementation (Step 7)
  - Steering Committee "Interested Party" guidelines finalized

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VICH - 9th Steering Committee Meeting

- Results (continued)
  - Topics scheduled for discussion at next meeting: GMP for pharmaceuticals, common technical document; efficacy of mastitis products; residues; ICH documents w/VICH impact
  - CAMEVET request for Observer status discussed; additional information requested
- VICH 2 Public Conference scheduled for October 9-11, 2002, in Tokyo
- Next meeting: November 27-28, 2001, in Tokyo

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VICH II
What are VICH Public Conferences?

- Modeled after ICH Public Conferences
- VICH I - Brussels, October 1999
- Provided an overview and update of current activities
- Goal - Conference every 2-3 years
- October 9-11, 2002, in Tokyo
- Asia/Pacific rim & Americas involvement

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VICH

Draft Guidelines

released for consultation (step 4 and beyond)

CONTENTS

2 November 1999

Active VICH Working Groups

VICH Biologics Working Groups

Topic	Chair	Leader	CVB rep.
Quality Guidelines	JMAFF		Morgan
-Stability		FDA	
Target Animal Safety	JVPA/JAVB		Gatewood
Good Clinical Practice	FEDESA	FEDESA	Elsken
Biologics Quality	JMAFF		
-Extraneous agents		FEDESA	Levings
-Mycoplasma		CVB (Levings)	Christianson
-Moisture and Formaldehyde		AHI	Ross
Pharmacovigilance	CVM		
-Information Technology		AHI	
-Reporting and Terminology		EU	Siev

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VICH Working Groups
Bio Quality - Moisture

- Step 5 Document under discussion (consultation just ended)
- Collaborative study conducted in 3 regions with 11 participants
- Controlled Environment, less than 45% Relative Humidity
- Manuscript of collaborative study being prepared
- Next meeting October 2001 in Strasbourg

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VICH Working Groups
Bio Quality - Formaldehyde

- Step 5 Document under discussion (consultation just ended)
- Collaborative study of EU Method B (Ferric Chloride Method) conducted in 3 regions with 11 participants
- Alternate low speed centrifuge for breaking oil emulsion
- Manuscript of collaborative study being prepared
- Draft Standard Requirements to implement guideline
- Next meeting October 2001 in Strasbourg

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VICH Working Groups
Bio Quality - Mycoplasma

- Step 2 document under discussion
- Deleted PCR as required test
- Future sensitivity study using European References
- Parts of production process which needs testing, still to be determined
- Attempting to work out differences in Step 2 document via e-mail
- Next meeting October 2001 in Strasbourg

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VICH Working Groups
Bio Quality - Extraneous Agents

- Divided guideline into mammalian and avian vaccines produced in cell lines
- Fish vaccines and vaccines produced in primary cells may follow
- List of agents tested for is still to be decided
- Issue of testing final product or Master Seed primary topic for discussion
- Next meeting October 2001 in Strasbourg

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VICH Working Groups
Quality - Stability

- Stability testing of new substances and products
- Proteins and polypeptides produced using rDNA technology
- Step 7 Guidelines released for implementation July 2000
- Veterinary Services Memorandum 800.300 published July 2001

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VICH Working Groups
Good Clinical Practice

- Step 7 Guideline released for implementation July 2000
- Veterinary Services Memorandum 800.301 published July 2001

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VICH Working Groups Pharmacovigilance

- Step 6 Guideline was not released for implementation by the Steering Committee
  - Issues include: Third country reporting; definition of adverse events/reactions; summary/safety report
- Step 4 Draft Guidelines released for consultation (December 31, 2001)
  - Management of Periodic Summary Update Reports
  - Controlled list of terms
- Next meeting October 2001 in EU

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VICH Working Groups Target Animal Safety

- JVPA/JVBA Topic Leader
- May 2001, Berlin, Germany
- Phased approach with Biologics coming second (~Fall 2001)
- Biologics concept paper finalized
- April 11, 2001, Public Workshop in conjunction with annual Public Meeting, Ames, Iowa
- Next meeting Fall 2001 in US

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VICH Working Groups
Anthelmentics

- Step 7 Guidelines released for implementation (July 2002)
  - Efficacy for equines, porcines, canines, felines, poultry
- Working Group concluded

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VICH Working Groups Antimicrobial Resistance

- Step 4 Draft Guidelines released for consultation (December 31, 2001)
  - Pre-approval studies
- Next meeting March 2002 in EU

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VICH Working Groups
Safety and Microbial Safety

- Step 4 Draft Guidelines released for consultation (December 31, 2001)
  - Carcinogenicity
- Step 7 Guidelines released for implementation (July 2002)
  - Drug residue studies: reproduction
  - Drug residue studies: genotoxicity
- Next meeting October 2001 in Tokyo

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VICH Working Groups
Ecotoxicity

- Step 2 Guideline still under discussion
- Next meeting October 2001 in Tokyo

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VICH Process

1. Steering Committee defines priority item from a concept paper. A Working Group is established (if needed), a Topic Leader is selected, and a mandate is provided
2. An expert Working Group drafts a recommendation
3. Steering Committee approves release of draft for consultation

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VICH Process

4. Draft recommendation is circulated for consultation
5. Working Group reviews comments and a Government representative assumes role of Topic Leader
6. Revised draft recommendation is submitted to the Steering Committee for approval

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VICH Process

7. Final recommendation and proposed draft is circulated to relevant regulatory authority
8. Steering Committee reports back on implementation progress
9. Recommendations are revised to take into account new scientific evidence

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US Implementation of VICH Guidelines

- Issue guidance documents
- Federal Rulemaking
- Implement within VICH timelines

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US Implementation of VICH Guidelines

July 13, 1999

CENTER FOR VETERINARY BIOLOGICS NOTICE 99-17

Subject: International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH): Request for Comments Regarding Proposed Guidelines for Technical Requirements

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

The purpose of this notice is to provide background on methods the Center for Veterinary Biologics (CVB) is using to assist in the development of harmonized international standards for veterinary biologics, to outline the CVB strategy for adopting these harmonized guidelines, and to encourage comments from interested parties on draft guidelines as they are published in the Federal Register.

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Monitoring VICH Activities

- Web sites
  - www.aphis.usda.gov/vs/cvb/
  - www.fda.gov
  - vich.eudra.org
- Federal Register Notices and Rules
- Center for Veterinary Biologics Notices and Veterinary Services Memoranda
- Steering Committee Members
- Working Group Experts

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